JAN 12 2007

K062670

5.0 510(k) SUMMARY

In accordance with Title 21 Code of Federal Regulations (21 CFR), Part 807, and in particular, §807.92, the following 510(k) summary is provided for the *VertiFlex™ Spinal Screw System*:

5.1 Submitted By:

VertiFlex™, Incorporated
1954 Kellogg Avenue, Suite 100
Carlsbad, California 92008

Contact: Steve Reitzler, Vice President of Regulatory & Quality Assurance

Date Prepared: September 5, 2006

5.2 Device Name

Trade or Proprietary Name:	*VertiFlex™ Spinal Screw System*
Common or Usual Name:	Pedicle Screw System
Classification Name:	Pedicle Screw Spinal System
Classification Regulation:	21 CFR, §888.3070
Product Codes:	MNH, MNI, NKB

5.3 Predicate Devices

The subject device is substantially equivalent, in whole or in part, to the following commercially available predicate devices:

UCR Spinal System (Seaspine; K043232)
VIPER™ Spine System (DePuy; K061520)
Xia® Spinal System (Stryker; K060979)
Click'X® System (Synthes; K031175)
ST360™ Spinal Fixation System (Zimmer; K041925)
CD HORIZON® Spinal System (Medtronic Sofamor Danek; K043343)
PathFinder™ Spinal System (Spinal Concepts; K030625)

5.4 Device Description

The *VertiFlex™ Spinal Screw System* is a posterior, non-cervical instrumentation system consisting of both pedicle screws and rigid connecting rods. Screws are of polyaxial or monoaxial (fixed) top-loading design, are composed of titanium alloy, and are available in a range of diameters and lengths to accommodate physiological requirements. The rods are composed of titanium, and are available in both straight and curved (pre-lordosed) styles, and in a range of lengths to accommodate both single-level and multiple levels procedures. The *System* may be implanted by either conventional surgical methods, or via minimally-invasive/percutaneous techniques. Manual instrumentation for implantation of the *System* is available for both conventional and minimally-invasive procedures. Screws, rods, and instruments are offered non-sterile.

5.5 Intended Use

The subject device is indicated for use as follows:

When used as a posterior, noncervical pedicle screw system, the VertiFlex™ Spinal Screw System *is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine:*

- *Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;*
- *Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra;*
- *Degenerative spondylolisthesis;*
- *Trauma (i.e., fracture or dislocation);*
- *Spinal stenosis;*
- *Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);*
- *Tumor;*
- *Pseudoarthrosis; and/or*
- *Failed previous fusion.*

5.6 Comparison to Predicate Devices

Testing and comparisons of design characteristics and features have established that the subject *VertiFlex™ Spinal Screw System* is substantially equivalent in design, materials of composition, indications, performance, and other features, to other predicate pedicle screw spinal systems commercially available in the U.S.

5.7 Summary of Non-Clinical Tests

Non-clinical tests, including those conducted in accordance with such recognized standards as ASTM F1717-04, *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*, have demonstrated the substantial equivalence of the subject device to commercially-available predicate devices in terms of performance.

5.8 Summary of Clinical Tests

No clinical testing was conducted to support this submission.

5.9 Conclusions

The results of all testing and comparison demonstrated the substantial equivalence of the subject device to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

VertiFlex™, Incorporated
% Mr. Steve Reitzler
Vice President, Regulatory Affairs
and Quality Assurance
1954 Kellogg Avenue, Suite 100
Carlsbad, California 92008

JAN 12 2007

Re: K062670
Trade/Device Name: VertiFlex™ Spinal Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI,
Dated: September 5, 2006
Received: September 7, 2006

Dear Mr. Reitzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062670

Device Name: *VertiFlex™ Spinal Screw System*

Indications for Use:

When used as a posterior, noncervical pedicle screw system, the *VertiFlex™ Spinal Screw System* is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
- Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra;
- Degenerative spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and/or
- Failed previous fusion.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Lorraine Preskup

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062670